

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

LUIGI WARREN,

Plaintiff,

vs.

THE CHILDREN'S HOSPITAL
CORPORATION,

Defendant

Civ. A. No. 17-12472-DLC

DEFENDANT'S STATEMENT OF UNDISPUTED MATERIAL FACTS

Pursuant to Local Rule 56.1, the defendant states that the following facts are undisputed.

A. Dr. Luigi Warren

1. Dr. Luigi Warren is a biologist who holds a Bachelor of Science degree in electrical engineering and computer science from the University College of London, a Bachelor of Science degree in biology from Columbia University, and a PhD in biology from Caltech, earned in 2008. (Warren Dep. at 8:15-9:4)¹.
2. While earning his PhD at Caltech, Dr. Warren worked in several labs at Caltech, and then joined Dr. Steve Quake's lab when it moved to Stanford. (*Id.* at 10:7-11:20).
3. Dr. Warren worked as a post-doctoral researcher in Dr. Derick Rossi's lab at the Immune Disease Institute (IDI) in Boston from approximately 2007 to 2010. (*Id.* at 11:21-12:10; 12:17-18).
4. IDI was an independent, Harvard-affiliated research institution. (*Id.* at 77:9-13).

¹ An excerpt of Dr. Luigi Warren deposition transcript, taken on November 16, 2019 is attached as SUMF Exhibit 1.

5. In 2010, Dr. Warren left IDI, after some professional differences arose between him and Dr. Rossi, relating primarily to the Rossi Lab's strategy for selecting journals in which to publish its results. (Warren Dep. 12:4-10; 50:9-53:6).
 6. After his departure from Dr. Rossi's lab, Dr. Warren joined the Yakin lab at MIT (*Id.* at 12:11-13).
 7. From 2010-2012, Dr. Warren worked as a self-employed consultant, consulting on cell-reprogramming and other closely related topics that he had worked on while at Dr. Rossi's lab. (*Id.* at 12:19 – 13:6).
 8. In or after 2012, Dr. Warren founded Stemiotics, a company involved in cell reprogramming. (*Id.* at 19:15-23).
 9. Stemiotics had licensed modified nucleotide technology from a company called Cellscript. After the company encountered difficulty in sublicensing this technology as part of its attempted sales to pharmaceutical companies, Dr Warren dissolved the company and in 2016, he started a new firm, Cellular Reprogramming, which did not rely on the technology licensed from Cellscript. (*Id.* at 19:24-21:19).
 10. Dr. Warren never became an employee of Boston Children's Hospital. (*Id.* at 84:13-15).
- B. Technology Transfer and Revenue Sharing, Generally.
11. Ryan Dietz was a Technology Transfer Associate and later Director of the Office of Technology Development at IDI from 2002 to 2012. Dietz moved to BCH in 2012 when the two institutions merged, and Dietz is currently the Senior Licensing Manager at BCH's Technology and Innovation Development Office. (Dietz Decl. ¶ 1).
 12. The work Drs. Rossi and Warren did was not federally funded (Warren Dep. 88:14-16; Dietz Decl. ¶ 3).

13. Even when work is not federally funded, many institutions have policies that provide for the sharing of royalties with inventors. IDI and Boston Children's Hospital (BCH) implemented such policies. (Dietz Decl. ¶ 3).

14. Even when not legally obligated to do so, these institutions elect to share revenues with inventors in their employ not only because they recognize it is fair and equitable, but also because it fosters relationships between the scientists and the institutions, leading to improved retention and better incentives for the scientists to make discoveries that others can commercialize for the benefit of the public. (*Id.* ¶ 4).

C. IDI's Policy.

15. At all times relevant to this case, IDI's policy was embodied in the Research and Technology Policy dated October 28, 2004 ("the IDI Policy"). (Dietz Decl. ¶ 3).

16. The IDI Policy provided that IDI would share one-third of the licensing revenue with inventors. (Warren Ex. 4 at 9)².

17. The IDI Policy also provided that IDI's trustees "retain the discretion to amend this policy from time to time." (*Id.* at 4).

18. The IDI Policy provided that "Equity received by IDI in lieu of a Licensing Fee shall be deemed a royalty." (*Id.* at 10).

19. The IDI Policy also provided that "equity taken as a royalty" should be distributed to inventors "at the earliest opportunity following receipt." (*Id.*).

20. Dr. Warren did not see the IDI Policy until long after his employment with IDI had ended. (Warren Dep. at 75:19-76:13).

² A true copy of Exhibit 4 from Dr. Luigi Warren deposition, taken on November 16, 2019 is attached as SUMF Exhibit 3.

D. Dr. Warren and Dr. Rossi's Discovery

21. In Dr. Warren's time at the Rossi Lab, between 2007-2010, he and Dr. Rossi invented a new and important technique for "reprogramming" cells in order to induce them to become pluripotent stem cells. (Warren Dep. at 16:11-19:6).
22. At the time, there were known techniques for creating induced pluripotent stem cells. For example, Dr. Yamanaka had invented a technique that injected cells with a virus that would carry "genes associated with the embryonic state" into a cell and integrate those genes with the cell's genome, so that after a few weeks in which the cell expressed the proteins coded by those genes, the cell would "regress to [the] embryonic state." (*Id.* at 14:12-23).
23. These known techniques had problems. Techniques that modified the genome carried with them a risk of cancer. (*Id.* at 15:2-11).
24. Drs. Warren and Rossi made an important advance by using synthetic messenger RNA ("mRNA") to cause cells to express the proteins that would cause them to regress to the embryonic state. (*Id.* at 36:21-37:19).
25. The main advantage of this technique is that mRNA is short-lived, and after the cell had been reprogrammed, the scientists simply stopped injecting it into the cells. The vector that expressed the gene as a result of the synthetic mRNA was biodegradable. Thus there was no risk of cancer, as there was when the genome of the cell was altered to include the genes for producing the necessary proteins. (*Id.* at 16:4-10)
26. Drs. Warren and Rossi submitted their invention disclosure to IDI on or about May 20, 2010 (Warren Ex. 3³; Warren Dep. 46:23-47:15), though Dr. Rossi may have informed

³ A true copy of Exhibit 3 from Dr. Luigi Warren deposition, taken on November 16, 2019 is attached as SUMF Exhibit 2.

IDI's technology transfer office about their work to date orally in August 2008. (Warren Dep. 47:4-11).

E. The Affiliation, the Merger, and IDI's Adoption of BCH's Policy.

27. When Dr. Warren joined the Rossi Lab, the lab was part of IDI, at that time an independent, Harvard-affiliated research institution. (Warren Dep. 77:9-13).

28. On December 24, 2008, IDI entered into an Affiliation Agreement with BCH's corporate parent, The Children's Medical Center Corp., in contemplation of an eventual merger. (Warren Ex. 15)⁴.

29. The Affiliation Agreement provided:

All IDI Intellectual Property Rights not previously licensed as of the Effective Time shall at the Effective Time be subject to the policies and procedures established by CMCC with respect to intellectual property of CMCC and/or its affiliates, as the same may be amended from time to time; provided, however, that this section shall not apply to any IDI Intellectual Property Rights subject to the GSK Agreement.⁵ (*Id.* at 25).

30. IDI did adopt BCH's relevant policies, including its policy on sharing revenues with inventors, at the Effective Time of the Affiliation Agreement. (Dietz Decl. ¶ 5).

31. The "Effective Time" was defined to be the day on which "the Amended and Restated Articles of Organization" that IDI was to file with the Secretary of the Commonwealth were "approved and filed by the Secretary," unless the parties agreed on another date. (Warren Ex. 15 at 2). The Amended and Restated Articles were filed and approved on February 20, 2009, which is therefore the Effective Time. (Folkman Decl. Ex. 1).

⁴ A true copy of Exhibit 15 from Dr. Luigi Warren deposition, taken on November 16, 2019 is attached as SUMF Exhibit 7.

⁵ The "GSK Agreement" was an unrelated intellectual property agreement that has no relationship with this case. (Dietz Decl. ¶ 5 n.1).

32. The BCH policy that IDI adopted at the Effective Time, embodied in the “Children’s Hospital Policy on Inventions and Intellectual Property” was dated April 21, 1992 and amended in 1993 (“the BCH Policy”). (Deitz Ex. 18 at 3)⁶.
33. The BCH Policy, like the IDI Policy, provided that employees are obligated to assign their inventions to the Hospital. (*Id.* at 1, 2).
34. The BCH Policy provided that the percentage of net revenues that an inventor would receive would decrease as the total amount of net revenues the Hospital received grew. (Deitz Ex. 18 at 3).
35. The BCH Policy also provided that a significantly lower percentage of net revenues would be shared with *former* Hospital employees than with *current* Hospital employees. (*Id.*)
36. Specifically, under the BCH Policy, inventors who remain employed by the Hospital, receive 70% of the first \$100,000 in net revenues, 45% of the next \$400,000, and 25% of remaining net revenues. (*Id.*) Inventors who are not Hospital employees receive 35% of the first \$500,000 in net revenues and only 25% of the remainder. (*Id.*)
37. The date that the Hospital uses to determine what percentage of licensing revenues it will share with inventors is the date of the license agreement. (Dietz Decl. ¶ 11).
38. IDI merged with BCH effective September 28, 2012. BCH was the surviving entity. (Folkman Decl. Ex. 2).

F. IDI Licenses The Invention To Moderna.

39. IDI exclusively licensed the Invention to Moderna Therapeutics, Inc. on December 21, 2010. (Warren Dep. Ex. 8)⁷.

⁶ A true copy of Exhibit 18 from Ryan Dietz deposition, taken on December 6, 2018 is attached as SUMF Exhibit 9.

⁷ A true copy of Exhibit 8 from Dr. Luigi Warren deposition, taken on November 16, 2019 is filed under seal as

40. On March 16, 2012, IDI and Moderna entered into an Amended and Restated Exclusive License Agreement. (Warren Dep. Ex. 8; Dietz Decl. ¶ 5). The license agreements were negotiated after IDI and BCH had affiliated. (Dietz Decl. ¶ 5).

41. The Amended and Restated Exclusive License Agreement provided [REDACTED]

[REDACTED]

[REDACTED] (Warren Ex. 8 at 18) [REDACTED]

[REDACTED]

[REDACTED]

(*Id.* at 18-21). [REDACTED] (*Id.* at 22; Warren Dep. at 91:6-16).

42. In the Affiliation Agreement, BCH and IDI agreed that the Hospital's policies for licensing would apply to all intellectual property matters, and thus, the license agreement with Moderna used the Hospital's form. (Dietz Decl. ¶ 5).

G. Dr. Warren's First And Second Assignments

43. IDI required its employees to assign inventions they made in the course of their employment as a condition of their employment (*Id.* ¶ 6).

44. Dr. Warren understood that it is standard practice for research institutions to require its scientists who are doing inventive work to assign their inventions to the institutions as a condition of employment. He understood that this was the policy of IDI, and of the other research institutions where he had previously worked, including Caltech and MIT. (Warren Dep. 83:12-85:1). Dr. Warren also understood that it was the policy of BCH to require such assignments from employees. (*Id.* at 84:16-22).

45. Before IDI filed its first application for a patent claiming the Invention, in or around April 2010, Dr. Warren assigned his rights in the Invention to IDI. (*Id.* at 68:9-18; Dietz Decl. ¶ 6).
46. In a February 2011 email correspondence, Ryan Dietz requested that Dr. Warren sign an additional assignment of the same invention. Dietz explained to Dr. Warren that an additional provision application was being filed to account for newly available data, and that a second assignment would be required in the Patent Office filings. (Warren Ex. 5)⁸
47. Dr. Warren was reluctant to execute the assignment, and he asked for copies of the documents containing the policies of employment at IDI that required him to assign his inventions. (Warren Ex. 5).
48. Mr. Dietz responded with the requested language, indicating that inventions are the sole and exclusive property of IDI, and the employed scientist agrees to execute an assignment to the entire right, title and interest in and to all inventions. (*Id.*).
49. Dr. Warren then asked a “follow up” question regarding IDI’s revenue sharing policies. Dr. Warren had recalled Dr. Rossi outlining those policies and asked Mr. Deitz for the language of those IDI policies. (*Id.*).
50. Mr. Dietz then responded detailing the licensing revenue share according to the IDI policy. (*Id.*).
51. Although Dr. Warren asked for the IDI policy on revenue sharing, and Mr. Dietz responded by providing the details of that policy, the revenue sharing policy that was in effect was in fact the BCH policy. (Dietz Decl. ¶¶ 5, 7).

⁸ A true copy of Exhibit 5 from Dr. Luigi Warren deposition, taken on November 16, 2019 is attached as SUMF Exhibit 4.

52. When Dr. Warren still would not execute the assignment, the General Counsel of BCH, Dianne McCarthy, sent a letter to Dr. Warren on IDI's behalf. The letter similarly explained the necessity of obtaining a second assignment, and the Dr. Warren's obligation to assign. The email enclosed IDI's Research and Technology Development Policy. The letter noted that the policy also benefits inventors. (Warren Ex. 6)⁹.

53. Although the BHC counsel's letter to Dr. Warren cited to the enclosed the IDI policy as the basis of IDI employees' obligation to assign inventions, the revenue sharing policy that was in effect at the time the letter was sent was in fact the BCH policy. (Dietz Decl. ¶¶ 5, 8).

54. Dr. Warren did execute the second assignment of his rights after receipt of the letter from BCH's general counsel. (Warren Dep. 72:22-73:18; Deitz Decl. ¶¶ 7-8).

H. The Hospital Treats Dr. Warren Just As It Treats Dr. Rossi.

55. Although Dr. Warren testified that he felt that the invention was "morally [his]" on account of his key role in the idea and the laboratory work (Warren Dep. 79:10-12), he agreed that it was fair that he and Dr. Rossi should share the inventors' share of the royalties equally: "I've never tried to . . . suggest that we should have other than a 50/50 split." (*Id.* at 79:2-14).

56. The Hospital did apply a 50/50 split of the royalties between Drs. Rossi and Warren. (Dietz Decl. ¶ 9).

57. In November 2017, Dr. Rossi negotiated with the Hospital for a better deal on for inventors for the Rossi/Warren invention. (*Id.*)

⁹ A true copy of Exhibit 6 from Dr. Luigi Warren deposition, taken on November 16, 2019 is attached as SUMF Exhibit 5.

58. Under the Hospital's usual policy, inventors who remain employed by the Hospital, such as Dr. Rossi, receive 70% of the first \$100,000 in net revenues, 45% of the next \$400,000, and 25% of remaining net revenues. (Dietz Ex. 18 at 3).
59. Under the Hospital's usual policy, inventors who are not Hospital employees, such as Dr. Warren, receive 35% of the first \$500,000 in net revenues and only 25% of the remainder. (*Id.*).
60. Dr. Rossi and the Hospital agreed that on this transaction, inventors should receive 27.5% of all net revenues. (Warren Ex. 17 at 1)¹⁰.
61. Dr. Warren was the one stakeholder who refused to approve the *ad hoc* policy Dr. Rossi worked out with the Hospital. (Warren Dep. 150:12-17; Warren Ex. 17 at 2).
62. Nevertheless, the Hospital is giving Dr. Warren the benefit of the *ad hoc* policy, because it is fair that he should be treated just as his co-inventor is being treated. (Dietz Decl. ¶ 10).
63. In the event an inventor dies during the term of a license, the Hospital's uniform practice is to pay that inventor's share of revenues to his or her estate. (Deitz Decl. ¶ 12).

I. The Moderna IPO.

64. On November 9, 2018, Moderna filed a Form S-1 with the Securities and Exchange Commission, indicating an intention to make an initial public offering of its common stock. *See* Moderna Form S-1, <https://www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473ds1.htm>.¹¹

¹⁰ A true copy of Exhibit 17 from Dr. Luigi Warren deposition, taken on November 16, 2019 is attached as SUMF Exhibit 8.

¹¹ A true copy of Moderna S-1 filed with the Security and Exchange Commission, on November 9, 2018 is attached as SUMF Exhibit 10.

65. Moderna made its IPO on December 6, 2018, raising more than \$600 million in the market. *See* Corrie Driebusch & Jonathan D. Rockoff, *Moderna IPO Raises Over \$600 Million in Rocky Market*, Wall Street Journal (Dec. 6, 2018), <https://www.wsj.com/articles/highly-anticipated-moderna-listing-is-seen-as-test-of-new-ipos-1544092200>

66. Even prior to this IPO, the Hospital's "reasonable assumption" was that its Moderna stock alone, leaving aside expected royalties, would be worth "tens of millions of dollars." (Dietz Dep. 80:9-17).

J. Dr. Warren's Theory of Harm.

67. Dr. Warren seeks an injunction requiring the Hospital to transfer shares of Moderna stock to him but does not seek damages. (Compl., ECF 1 at 4-5).

68. Had the shares been transferred to Dr. Warren, he could not have sold the shares until December 2018, when Moderna went public, at the earliest (Warren Dep. 109:17-110:5)

69. Moderna has never paid a dividend (Moderna Form S-1, *supra*, at 81)

70. The only reason Dr. Warren claims the receipt of stock rather than the proceeds of the sale of the stock could matter to him is the difference in tax treatment he says he would have received in the two cases. Specifically, Dr. Warren maintains that had he received the shares earlier, he would have been able to sell them at a future date and pay the favorable capital gains tax rate on the gains rather than paying the tax on ordinary income. (Warren Dep. 110:6-16).

71. Dr. Warren has refused to identify his accountant, claiming that the name of his accountant is privileged. (*Id.* at 64:13-65:3).

Respectfully submitted,

THE CHILDREN'S HOSPITAL
CORPORATION

By its attorneys:

/s/ Theodore J. Folkman

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Dated: February 15, 2019

CERTIFICATE OF SERVICE

I, Theodore J. Folkman, hereby certify that, in accordance with Local Rule 5.2(b), the foregoing document was filed through the ECF system on February 15, 2019 and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Theodore J. Folkman

Theodore J. Folkman